

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE NEW YORK TIMES COMPANY and	:	
KATE KELLY,	:	
	:	
Plaintiffs,	:	
	:	<u>COMPLAINT</u>
v.	:	
UNITED STATES FOOD & DRUG ADMINISTRATION,	:	
	:	
Defendant.	:	
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Plaintiffs THE NEW YORK TIMES COMPANY and KATE KELLY, by and through their undersigned attorneys, allege as follows:

1. This is an action under the Freedom of Information Act, 5 U.S.C. § 552 et seq. (“FOIA”), to obtain an order for the production of agency records in response to a FOIA request properly made by Plaintiffs The New York Times Company and Kate Kelly (jointly, “The Times”) to the United States Food & Drug Administration (“FDA”).

PARTIES

2. Plaintiff The New York Times Company publishes *The New York Times* newspaper and www.nytimes.com. The New York Times Company is headquartered in this judicial district at 620 Eighth Avenue, New York, NY 10018.

3. Plaintiff Kate Kelly is a correspondent with *The New York Times*.

4. Defendant FDA is the agency within the federal government that has possession and control of the records that Plaintiffs seek.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 552(a)(4)(B).

6. Venue is premised on Plaintiffs' place of business and is proper in this district under 5 U.S.C. § 552(a)(4)(B).

7. FOIA requires that agencies respond to FOIA requests within 20 business days. *See* 5 U.S.C. § 552(a)(6)(A).

8. Defendant FDA has failed to meet the statutory deadlines set by FOIA. *See* 5 U.S.C. § 552(a)(6)(A)–(B). Plaintiffs are therefore deemed to have exhausted all administrative remedies pursuant to 5 U.S.C. § 552(a)(6)(C).

FACTS

9. Oral contraceptives, the most popular form of nonpermanent birth-control in the United States, have traditionally been available in the United States only with a doctor's prescription. Recently, many have advocated for making them available over the counter, as is the norm in many other countries, including the United Arab Emirates, China, and Mexico. *See* Kate Kelly, *Firms Push to Make Birth-Control Pills Available Without Prescriptions*, N.Y. Times (Dec. 14, 2021), <https://tinyurl.com/2hcwej5f>.

10. Reproductive rights activists view over-the-counter birth-control pills as “easy and effective tool[s] for rural, poor and historically marginalized communities to avoid unwanted pregnancies—reducing their barriers to health care and lowering the abortion rate along the way.” *Id.*

11. This effort to make birth-control pills available over the counter has received congressional support. Representative Barbara Lee, for example, has said: “Access to over-the-

counter birth-control is a racial equity issue, a gender equity issue, and an economic equity issue. In the same way that other methods of birth-control are available over the counter, the pill should be too.” *Id.*

12. One drug company, HRA Pharma, applied to the FDA in July 2022 to make the switch from a prescription version to an over-the-counter version of oral contraceptives. *See* Sheryl Stolberg and Kate Kelly, *F.D.A. to Weigh Over-the-Counter Sale of Contraceptive Pills*, N.Y. Times (July 11, 2022), <https://tinyurl.com/5x42pvbn>. The company’s application was put on hold in October 2022 pending new questions about its drug, known as Opill, according to the November 2022 Form 10-Q filed by HRA Pharma’s parent company Perrigo. *See* Perrigo Company plc, Form 10-Q (Nov. 8, 2022), at 51, <https://tinyurl.com/5n6bf9pc>.

13. On December 6, 2021, The Times submitted a FOIA request (“the Request”) to the FDA, seeking “any and all communications between FDA staff and drug sponsors seeking to make an Rx to OTC switch through the nonprescription drug office for oral contraceptives.” The FDA acknowledged receipt of the request the same day.

14. On December 10, 2021, the FDA denied The Times’s request for expedited processing, stating that The Times did not demonstrate that there was a “compelling need.”

15. On December 17, 2021, The Times appealed the FDA’s denial of expedited processing, arguing, in part, that the denial was erroneously premised on the agency’s implicit assumption either that debates related to reproductive rights are not of great public and media importance or that issues surrounding the availability of oral contraceptives are unrelated to the reproductive rights debate.

16. On April 1, 2022, the FDA upheld its decision to deny the request for expedited processing.

17. As of the date of this filing, the FDA has not released any responsive records to The Times or otherwise informed The Times that it has made a final determination on the Request.

CAUSE OF ACTION

18. Plaintiffs repeat, reallege, and reincorporate the allegations in the foregoing paragraphs as though fully set forth herein.

19. Defendant is an agency subject to FOIA and must therefore release in response to a FOIA request any disclosable records in its possession at the time of the request and provide a lawful reason for withholding any other materials as to which it is claiming an exemption.

20. Defendant has failed to meet the statutory deadlines set by FOIA. 5 U.S.C. § 552(a)(6)(A)–(B). Accordingly, Plaintiffs are deemed to have exhausted their administrative remedies under FOIA.

21. Defendant is permitted to withhold documents or parts of documents only if one of FOIA's enumerated exemptions applies.

22. No exemptions permit the withholding of the documents sought by the Request.

23. Accordingly, Plaintiffs are entitled to an order compelling Defendant to produce records responsive to the Request.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

24. Declare that the documents sought by the Request, as described in the foregoing paragraphs, are public under 5 U.S.C. § 552 and must be disclosed;

25. Order Defendant to undertake an adequate search for the requested records and provide those records to Plaintiffs within 20 business days of the Court's order;

26. Award Plaintiffs the costs of this proceeding, including reasonable attorneys' fees, as expressly permitted by FOIA; and

27. Grant Plaintiff such other and further relief as this Court deems just and proper.

Dated: New York, NY
December 27, 2022

/s/ David E. McCraw
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